

# Hantavirus Antigen Rapid Test Kit

## Instructions For Use

### PRODUCT NAME

Hantavirus Antigen Rapid Test Kit

### PACKAGE SPECIFICATION

25 tests/kit

### INTENDED USE

This kit is used for qualitative detection of Hantavirus (HV) antigen in human serum, plasma and whole blood samples in vitro, which plays an important role in the early diagnosis and treatment of Hantavirus infection, and can assist in the diagnosis of Hantavirus infection in clinical practice.

### SUMMARY AND PRINCIPLES OF THE PROCEDURE

Hantaviruses are enveloped, negative-sense RNA viruses belonging to the family Hantaviridae. They are transmitted to humans primarily through inhalation of aerosolized excreta from infected rodents. Hantavirus infection in humans can lead to two main clinical syndromes: hemorrhagic fever with renal syndrome (HFRS), caused predominantly by Old World hantaviruses (e.g., Hantaan, Seoul, Puumala, Dobrava viruses), and hantavirus pulmonary syndrome (HPS), caused by New World hantaviruses (e.g., Sin Nombre, Andes viruses). HFRS is characterized by fever, thrombocytopenia, and acute kidney injury, while HPS presents with fever, myalgia, and rapidly progressive respiratory failure. Both syndromes have significant case fatality rates, and no specific antiviral treatment is currently approved. Prevention relies on rodent control and avoidance of exposure.

Hantavirus Antigen Rapid Test Kit is a qualitative membrane-based immunoassay for the detection of Hantavirus Antigen in human whole blood, serum, or plasma specimens. The test device consists of: 1) a burgundy-colored conjugate pad containing anti-HV antibody conjugated with colloid gold, 2) a nitrocellulose membrane strip containing test line (T) and a control line (C). The test line (T) is pre-coated with another anti-HV antibody, and the control line (C) is pre-coated with goat anti mouse IgG. When an adequate volume of extracted specimen is added to the specimen well(S) of the device, the specimen migrates by capillary action across the device. If the specimen contains sufficient Hantavirus Antigen, a colored line(s) will appear in the test line region (T). Absence of test line suggests a negative result. An internal quality control is included in the test, in the form of a colored line appearing in the control line region (C), indicating that the test is functional, and proper and sufficient volume of specimen has been applied to enable migration through the test and control lines, regardless of whether there is a test line or not. If the control line (C) does not appear within the testing time, test result is invalid and the test should be repeated with a new test device.

### MATERIALS PROVIDED

#### Each kit contains:

1. Test Devices: 25 pieces test devices individually pouched.
2. Wash Buffer Solution: 3 ml in dropper bottle.
3. Droppers: 25 pieces droppers of 25 ul
4. Instructions For Use: 1 copy attached.

### MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch.
- Specimen collection containers
- Disposable gloves and/or protective clothing
- Centrifuge(for plasma only)
- Micropipette
- Lancets(for fingertip whole blood only)

### WARNINGS

1. Read the package insert completely before using the product. The instructions must be followed carefully as not doing so may result in inaccurate results.
2. The kit is for diagnostic use only.
3. Perform test at room temperature.

### PRECAUTIONS

1. The kit is for professional use only.
2. The package insert instructions must be followed to ensure optimum test performance.
3. The kit is intended for in vitro diagnostic use.

4. As with all screening assays, any results should be considered presumptive until confirmatory assays have been performed according to local practice or WHO guidelines.

### Safety Precautions

1. Standard precautions for handling infectious agents should be observed when using this kit.
2. Wear protective clothing such as lab coat, safety glasses and disposable gloves when handling specimens and assay reagents.
3. Wash hands thoroughly after use.
4. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

### Bio safety Precautions

Appropriate bio safety practices should be used when handling specimens and reagents. These precautions include, but are not limited to the following:

1. Do not smoke, eat, drink, apply cosmetics or handle contact lenses in areas in which specimens are handled.
2. Dispose of all specimens, used devices and tubes as though they are capable of transmitting infection. The preferred methods of disposal are by autoclave at 121 °C for a minimum of 60 minutes or by incineration. Disposable materials may be incinerated. Liquid waste may be mixed with appropriate chemical disinfectants. A solution of 10% bleach is recommended. Allow 60 minutes for effective decontamination. NOTE: Do not autoclave solutions containing bleach.
3. When disposing of wash buffer, avoid contact with acid to prevent liberation of a toxic gas.
4. All spills should be wiped thoroughly using a suitable disinfectant such as a sodium hypochlorite solution.
5. Use a separate dropper and device for each specimen tested.

### Handling Precautions

1. Do not use if the kit box safety seal is absent, damaged or broken.
2. Do not use any device if the pouches have been perforated.
3. Each device is for single use only.
4. Do not mix wash buffer solution/test devices from different kit lots.
5. Do not use the kit past the expiration date (this date is printed on the kit box).
6. Adequate lighting is required to read the test results.
7. The result should be read immediately after the end of the 10 minutes incubation time following the addition of specimen and wash buffer solution. Do not read results beyond 15 minutes.

### STORAGE INSTRUCTIONS

1. The Kit should be stored between 2-30°C and the shelf life is 24 months.
2. The Kit components are stable until the expiration date printed on the outer label, when stored as directed. The kit expiry date is determined by whichever of the components has the shortest expiry date. The kit expiry date is not impacted once the wash buffer solution has been opened. Do not use kit components beyond overall kit expiry date.
3. If stored refrigerated, ensure that the pouched device is brought to room temperature before opening.
4. Do not freeze the kit.

### SAMPLE COLLECTION AND PREPARATION

1. Applicable samples: Whole Blood/Serum/Plasma.
2. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear nonhemolysis specimens.
3. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods.
4. Serum and plasma specimens may be stored at 2-8°C for up to 7 days, for long term storage, serum/plasma specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8 °C if the test is to be run within 2 days of collection.
5. Do not freeze whole blood specimens.
6. Whole blood collected by finger stick should be tested immediately.
7. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
8. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiological agents.
9. EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

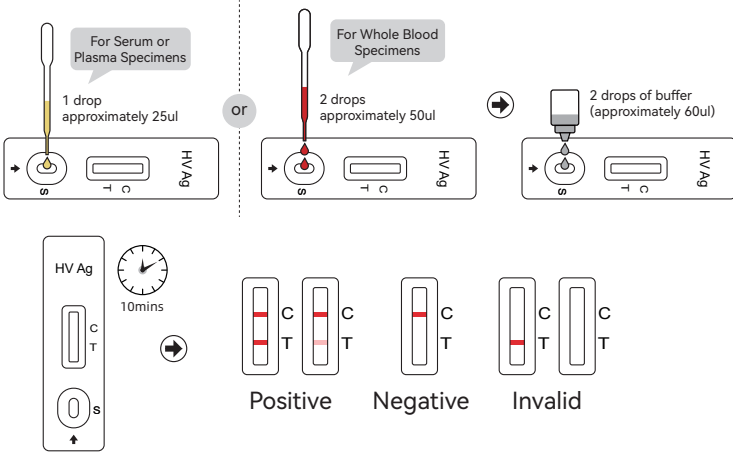
### QUALITY CONTROL

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal valid procedural control, it confirming adequate membrane wicking. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

### TEST PROCEDURE

Allow the test device, specimen, extraction solution to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the sealed pouch and use it within one hour. Place the test cassette on a clean and level surface.
2. For Serum or Plasma Specimens  
Hold the dropper vertically, draw the specimen and transfer the specimen to the sample well of the test cassette (one drop/approximately 25ul), then add two drops of buffer (approximately 60ul) to the sample well and start the timer. Avoid trapping air bubbles in the sample well.  
For Whole Blood Specimens  
Hold the dropper vertically, draw the specimen and transfer the specimen to the sample well of the test cassette (two drops/approximately 50ul), then add two drops of buffer (approximately 60ul) to the sample well and start the timer. Avoid trapping air bubbles in the sample well (**NOTE:** If the sample does not flow, you can add an extra drop of the buffer).
3. Wait for the colored line(s) to appear. The test result should be read at 10 minutes. Do not interpret the result after 15 minutes.



## INTERPRETATION OF RESULTS

**Negative result:** if there is only a quality control line C, the detection line is colorless, indicating that Hantavirus antigen has not been detected and the result is negative.

**Positive result:** if both the quality control line C and the detection line appear, the Hantavirus antigen has been detected and the result is positive.

**Invalid result:** if the quality control line C is not observed, it will be invalid regardless of whether there is detection line (as shown in the figure above), and the test shall be conducted again.

## LIMITATIONS

1. The kit is for in vitro diagnostic use only. The test should be used for the detection of Hantavirus antigen in serum, plasma or whole blood specimens only. Neither the quantitative value nor the rate of increase in Hantavirus antigen concentration can be determined by this qualitative test.
2. The kit will only indicate the presence of Hantavirus antigen in the specimen and should not be used as the sole criteria for the diagnosis of Hantavirus infection.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. The kit can detect the antigen in the early stage of hantavirus infection (approximately within 5-7 days after infection). As the infection progresses, the antigen content decreases, which may lead to false negatives. It is necessary to combine with other detection methods.

## PERFORMANCE CHARACTERISTICS

### Sensitivity and Specificity

Clinical samples (serum/plasma) confirmed Hantavirus antigen positive or negative by PCR test with the kit. The results indicated that the kit has a high sensitivity and specificity as summarized below:

Clinical study		PCR		
		Positive	Negative	Total Results
Hantavirus Antigen Rapid Test Kit	Result			
	Positive	34	2	36
	Negative	2	216	218
Total Results		36	218	254

### Accuracy Results:

Clinical sensitivity=94.44% (81.34% ~ 99.32%)

Clinical specificity=99.08% (96.73% ~ 99.89%)

Accuracy=98.43% (96.02% ~ 99.57%)

## Cross Reaction

The following organisms were tested with The kit and has no effect on the negative and positive test results of this reagent, and there is no cross-reaction: some closely related viruses at a concentration of  $1 \times 10^6$  copies/mL such as Puumala virus, Andes virus, Dengue virus, Japanese encephalitis virus, Zika virus, and common clinical bacteria at a concentration of  $1 \times 10^8$  CFU/mL such as Leptospira interrogans, Rickettsia rickettsii, Escherichia coli.

## Interfering Substances

The following compounds have also been tested using the Hantavirus Antigen Rapid Test Kit and no interference was observed. Hemoglobin: 5 g/L, Bilirubin: 342 µmol/L, Triglycerides: 10 mmol/L, RF: 1000 IU/mL, HAMA: 500 ng/mL.

## INDEX OF SYMBOL

	In vitro diagnostic medical device		single-use, Please don't reuse it
	Use-by date		Consult instructions for use
	Cautions		Manufacturer
	Temperature limit		Batch code
	Date of manufacture		Keep Dry
	Avoid overexposure to the sun		Don't use the product when the package is damaged
	Biological risks		